

# DEPARTMENT OF HEALTH AND SOCIAL SERVICES

## DIVISION OF HEALTH CARE QUALITY

Statutory Authority: 16 Delaware Code, Section 122(3)p. (16 Del.C. §122(3)p.)  
16 DE Admin. Code 4404

### FINAL

### ORDER

#### 4404 Free Standing Emergency Centers

##### **Nature of The Proceedings**

Delaware Health and Social Services ("DHSS") initiated proceedings to adopt the State of Delaware Regulations Governing Free Standing Emergency Departments. The DHSS proceedings to adopt regulations were initiated pursuant to 29 Delaware Code, Chapter 101 and authority as prescribed by 16 Del. C. §122 (3)(p).

On April 1, 2020 (Volume 23, Issue 10), DHSS published in the *Delaware Register of Regulations* its notice of proposed regulations, pursuant to 29 Del. C. §10115. It requested that written materials and suggestions from the public concerning the proposed regulations be delivered to DHSS by May 1, 2020, after which time DHSS would review information, factual evidence, and public comment to the said proposed regulations. On May 1, 2020 (Volume 23, Issue 11), DHSS published in the *Delaware Register of Regulations* its notice of extended comment period, pursuant to 29 Del. C. §10118(a). It requested that written materials and suggestions from the public concerning the proposed regulations be delivered to DHSS by May 29, 2020.

Written comments were received during the public comment period and evaluated. The results of that evaluation are summarized in the accompanying "Summary of Evidence."

##### **Summary of Proposal**

Effective January 1, 2021, DHSS/Division of Health Care Quality (DHCQ) is publishing the final regulations governing Free Standing Emergency Departments.

##### **Background**

Free standing emergency departments must meet the same standards as a hospital emergency department. Recent legislative changes clarified the scope of practice required of a free standing emergency department. This clarification provides a level of protection for the public that seek services in a free standing emergency department.

##### **Statutory Authority**

16 Del. C. §122(3)(p)

##### **Purpose**

The purpose of the amendment was to update the requirements to be consistent with nationally recognized standards of practice and to ensure patients receive safe and quality care in a free standing emergency department.

##### **Fiscal Impact**

N/A

#### **SUMMARY OF EVIDENCE**

##### **STATE OF DELAWARE REGULATIONS GOVERNING FREE STANDING EMERGENCY DEPARTMENTS**

In accordance with Delaware Law, public notices regarding proposed Department of Health and Social Services (DHSS) Regulations Governing Free Standing Emergency Departments were published in the *Delaware Register of Regulations*. Written comments were received on the proposed regulations during the public comment period (April 1, 2020 through May 29, 2020).

Public comments and DHSS' responses are as follows:

**Ann C. Fisher, Chairperson Governor's Advisory Council for Exceptional Citizens**



**Comment:** The Governor's Advisory Council for Exceptional Citizens (GACEC) has reviewed the Delaware Health and Social Services (DHSS)/Division of Health Care Quality (DHCQ) proposed regulations governing Free Standing Emergency Departments. Council endorses the proposed regulation; however we would like to share one observation.

The proposed regulation by the Department of Health and Social Services (DHSS), Division of Health Care Quality (DHCQ), abrogates the existing one (4404) and re-numbers it 3340. The proposed regulation changes the name of the facility from Free Standing Emergency Center to Free Standing Emergency Department (FSED). DHSS originally published proposed regulations for FSEDs in the July 1 2019 issue of the Delaware Register of Regulations. The regulations are being republished as the Department made significant substantive changes to the previous proposed regulations.

One of the comments on the earlier regulation was that it did not specifically mention the Americans with Disabilities Act of 1990 (ADA) or Section 504 of the Rehabilitation Act of 1973 (Section 504). The ADA requires access to medical care services and the facilities where the services are provided. Private FSEDs are covered by Title III of the ADA. Section 504 covers any FSED that received federal financial assistance (including Medicare and Medicaid reimbursements). Earlier commentary stated that it would be better if the regulation specifically mentioned that the FSED must comply with the ADA and Section 504, so that its application to persons with disabilities would be readily apparent (and not by inference). Section 4.23 of the proposed regulation now requires FSEDs to comply with the ADA and incorporates the act into the regulation. Likewise, section 4.24 requires FSEDs to comply with Section 504 and incorporates the act into the regulation.

Other recommendations were similarly accepted and changes have been made to the current proposed regulations. This regulation is a major effort to protect the citizens of Delaware and ensure they receive proper care from Free Standing Emergency Departments. The regulation is comprehensive and applies equally to all patients, including those with disabilities. The regulation specifically incorporates the ADA and Section 504. The regulation also requires a disability inclusive written disaster preparedness plan. Council appreciates the attempt by DHSS to ensure the quality of care and to regulate the provision of services patients receive from FSEDs. However, there is one area that would benefit from a change. Council would suggest that language be added to the fire safety section to more adequately address the needs of individuals with disabilities.

**Response:** Thank you for your comments. Per Section 15.0, the free standing emergency department must maintain a disability inclusive disaster preparedness plan to manage potential medical and non-medical emergencies, which includes fires. We will take your suggestion under advisement for future updates should this point need clarification in the future.

#### **J. Todd Webb, Chairperson, State Council for Persons with Disabilities (SCPD)**

**Comment:** The State Council for Persons with Disabilities (SCPD) has reviewed the Department of Health and Social Services' (DHSS) Division of Health Care Quality's (DHCQ's) proposed regulation which abrogates the existing one (4404) and re-numbers it 3340. The proposed regulation changes the name of the facility from Free Standing Emergency Center to Free Standing Emergency Department (FSED). DHSS originally published proposed regulations for FSED's in the July 1st, 2019 issue of the Delaware Register of Regulations. The regulations are being republished as the Department made significant substantive changes to the previous proposed regulations. The proposed regulation was published as 23 DE Reg. 817 in the April 1, 2020 issue of the Register of Regulations. SCPD has the following observations and recommendations.

SCPD reviewed the July 2019 proposed regulation and, one of the criticisms of the regulation was that it did not specifically mention the Americans with Disabilities Act of 1990 (ADA) or Section 504 of the Rehabilitation Act of 1973 (Section 504). The ADA requires access to medical care services and the facilities where the services are provided. Private FSED's are covered by Title III of the ADA. Section 504 covers any FSED that received federal financial assistance (including Medicare and Medicaid reimbursements). SCPD stated that it would be better if the regulation specifically mentioned that the FSED must comply with the ADA and Section 504 so that its application to persons with disabilities would be readily apparent (and not by inference).

Section 4.23 of the proposed regulation now requires FSED's to comply with the ADA and incorporates the act into the regulation. Likewise, section 4.24 requires FSED's to comply with Section 504 and incorporates the act into the regulation. SCPD appreciates and supports the revision.

Another criticism of the July 2019 regulation was that, although it mandated preparation of a written disaster preparedness plan for dealing with medical and non-medical emergencies, there was no specific language setting forth any requirements for dealing with patients with disabilities during an emergency. Section 15.2 of the proposed regulation now requires



FSED's to "maintain a disability inclusive written disaster preparedness plan for natural and other disasters specific to the facility." SCPD appreciates and supports the revision.

A third criticism of the July 2019 regulation was that, although it required FSED's to comply with the rules and regulations of the Fire Prevention Commission and be inspected annually by the fire marshal, there was no specific language dealing with how patients with disabilities would be evacuated. Further, the regulation did not require that employees receive training in procedures to be followed for patients with disabilities. SCPD recommended that it would be better if the regulation had requirements that specified an evacuation route for patients with disabilities, including the width of any route and removal of any obstructions. Unfortunately, this issue was not addressed in the proposed regulation.

The proposed regulation adds a host of new definitions, including abuse, medication diversion, adverse incident, and emergency care. However, if a FSED is owned and operated by a hospital and is accredited by an organization approved by the Centers for Medicare and Medicaid Services, it is exempt from licensure and this regulation.

The regulation establishes a comprehensive licensing procedure, which includes an initial license (3.3.1), a provisional license (3.3.2), and an annual license (3.3.3). The regulation vests the Department of Health and Social Services with the authority to impose disciplinary action, including immediately suspending a license where there is an "immediate jeopardy or imminent danger to the public health, welfare and safety requiring emergency action." (3.5).

The regulation also sets up a comprehensive scheme of authority and responsibility. Every FSED must have a governing body that is responsible for the management, control, and operation of the facility. (5.0). There must be a director who is a full-time physician board certified in emergency medicine. He or she is responsible for the day to day operation and management of the FSED. (6.1.1; 6.1.2). The director is responsible for providing quality medical care. (6.1.3).

There must be a clinical director appointed by the director who is a registered nurse with substantial education, experience, and competence in emergency nursing. (6.2.1; 6.2.3.1). He or she must be a competent manager, administrator, and supervisor since the person provides general supervision and direction of the services offered by the FSED. (6.2.3.2; 6.2.3.3).

There are requirements for physicians (6.7) and nurses (6.8). There must be at least one (1) physician and one (1) registered nurse with training "in advanced cardiac life support and pediatric advanced life support in the FSED at all times." (6.9).

The regulation requires FSED's to have an infection prevention and control program based upon nationally recognized guidelines and standards such as the Centers for Disease Control and Prevention. (8.1).

The FSED must be properly built, equipped, and maintained to protect the health and safety of patients and employees. (10.1). A facility must have an adequate supply of linen that is processed in accordance with national standards for healthcare laundry. (10.2.1; 10.2.8). An FSED must have housekeeping services to ensure a clean, sanitary, and safe environment. (10.3.1). Waste must be properly stored and disposed of to prevent the transmission of disease (10.4.3), and the regulation adopts and incorporates, as requirements for FSED's, the provisions of the Department of Natural Resources and Environmental Control Regulation Governing Solid Waste. (10.4.4).

FSED's have to collect, maintain, and store patient medical records (while protecting confidentiality), and must be able to retrieve, authenticate, and distribute a patient's medical records. Records can be kept in hard copy, electronically, or a combination of both. (11.0).

Drugs, controlled substances, and biologicals must be properly stored, accessible only to authorized employees, and prepared and dispensed "according to acceptable standards of practice." (12.1; 12.4). FSED's must comply with all state and federal laws, regulations and guidelines pertaining to pharmaceutical services (12.2), and must be registered under state and federal controlled substance acts. (12.3).

An FSED must provide a patient or patient's representative with verbal and written notice of the patient's rights (14.1) and also post the patient's rights in the waiting room. (14.2). The notice must include the contact information of DHSS to which patients may report complaints. (14.2). The patient's rights are broad and include treatment with respect and dignity; safety; privacy; care free from abuse, neglect, and exploitation; provision of appropriate information concerning the diagnosis, treatment and prognosis to the patient, patient's designee, or legally authorized person; participation in decisions involving care and treatment except "when the patient's participation is contradicted for medical reasons;" and the ability to complain about treatment and care that is or is not provided. (14.0 et. seq.) Information shall also be provided to patients and employees about patient conduct and responsibilities; services that the FSED provides; the fees and payment policies for



the available services; and ways to express complaints and suggestions to the FSED. (14.4 et. seq.).

This regulation is a major effort to protect the state's citizens and ensure they receive proper care from Free Standing Emergency Departments. The regulation is comprehensive and applies equally to all patients, including those with disabilities. The regulation specifically incorporates the ADA and Section 504. The regulation also requires a disability inclusive written disaster preparedness plan. That being said, SCPD still recommends that language be added to the fire safety section to more adequately address the needs of individuals with disabilities. This is a laudable attempt by DHSS/DHCQ to ensure the quality of care and to regulate the provision of services patients receive from FSED's.

SCPD endorses the proposed regulation.

Thank you for your consideration and please contact the SCPD if you have any questions regarding our observations or recommendation on the proposed regulation.

**Response:** Thank you for your comments. Per Section 15.0, the free standing emergency department must maintain a disability inclusive disaster preparedness plan to manage potential medical and non-medical emergencies, which includes fires. We will take your suggestion under advisement for future updates should this point need clarification in the future.

#### **Findings of Fact:**

There were no changes made to the regulations based on the comments received and detailed in the "Summary of Evidence." DHSS finds that the proposed regulations, as set forth in the attached copy, should be adopted in the best interest of the general public of the State of Delaware.

THEREFORE, IT IS ORDERED, that the proposed State of Delaware Regulations Governing Free Standing Emergency Departments is adopted and shall become effective January 11, 2021, after publication of the final regulation in the *Delaware Register of Regulations*.

12/11/2020

Date

Molly K. Magarik, Secretary, DHSS

### **44043340 Free Standing Emergency Centers Departments**

#### **4.0 Definitions**

~~"Free Standing Emergency Center" means a facility physically separate from a hospital, which uses in its title or in its advertising, the words "emergency", "urgent care", or parts of those words or other language or symbols which imply or indicate to the public that immediate medical treatment is available to individuals suffering from a life-threatening medical condition. The facility rendering such care is capable of treating all medical emergencies that have life-threatening potential.~~

#### **2.0 License Requirement**

- 2.1 ~~No person shall establish, conduct or maintain in this State any Free Standing Emergency Center without first obtaining a license from the Division of Public Health.~~
- 2.2 ~~Existing Institutions~~
  - 2.2.1 ~~No person shall continue to operate an existing Free Standing Emergency Center unless such facility is approved and regularly licensed by the State Board of Health as provided in this chapter.~~
- 2.3 ~~Trailblazing Signs~~
  - 2.3.1 ~~No Free Standing Emergency Center, treatment facility, office or station shall be authorized to exhibit any Trailblazing signs, symbols or directional signs by the State Highway Department unless such facility has been duly licensed under the provisions of this chapter.~~
- 2.4 ~~Transfer Agreement~~
  - 2.4.1 ~~The Free Standing Emergency Center shall have a written transfer agreement with one or more hospitals which provides the basis for effective working arrangements in which inpatient hospital care or other hospital services are available promptly to the facility's patients when needed.~~

#### **3.0 Application on for License and Ownership**



3.1 ~~Application for license to establish, maintain or operate a Free Standing Emergency Center shall be made to the Division of Public Health stating the location thereof, the name of the person in charge and all other information necessary to determine the qualifications of the applicant.~~

3.2 ~~Ownership~~

3.2.1 ~~The ownership and control of the facility and the property on which the Free Standing Emergency Center is located shall be disclosed to the Division of Public Health. Proof of this ownership must be produced upon request of authorized persons within three (3) working days. Any change in ownership shall be reported to Office of Health Facilities Licensing and Certification in writing prior to the change.~~

#### **4.0 Inspections**

4.1 ~~Every Free Standing Emergency Center for which a license has been issued under this chapter shall be periodically inspected by a representative of the Division of Public Health.~~

#### **5.0 Issuance of Licenses**

5.1 ~~Licenses shall be issued in the following categories:~~

5.1.1 ~~Annual License. An annual license (12 months) may be renewed yearly if the holder is in full compliance with the provisions of this chapter and the rules and regulations of the Division of Public Health.~~

5.1.2 ~~Provisional License. A provisional license shall be granted for a term of three (3) months only and shall be granted only to a Free Standing Emergency Center which, although not in full compliance, is nevertheless demonstrating evidence of improvement.~~

#### **6.0 Suspension or Revocation of License**

6.1 ~~The Division of Public Health may suspend or revoke a license issued under this chapter on any of the following grounds:~~

6.1.1 ~~Violation of any of the provisions of this chapter or the rules and regulations issued pursuant thereto.~~

6.1.2 ~~Permitting, aiding or abetting the commission of any illegal act in the facility.~~

6.1.3 ~~Conducts or practices detrimental to the welfare of the patient.~~

6.1.4 ~~Before any license issued under this chapter is suspended or revoked, one (1) month notice shall be given in writing to the holder of the license, during which time he may appeal for a hearing before the Division of Public Health.~~

6.2 ~~Emergency Suspension~~

6.2.1 ~~The Division of Public Health may suspend a license without a hearing if it finds that there is an immediate danger to the public health and safety which warrants this action. A hearing on the suspension should be scheduled before the Board no more than 30 days after the licensee is notified of the suspension. The suspension shall continue in effect until the conclusion of the proceedings, including judicial review thereof unless sooner withdrawn by the Division or dissolved by a court of competent jurisdiction.~~

6.3 ~~Renewal of License After Suspension on or Revocation on~~

6.3.1 ~~If and when the conditions upon which the suspension or revocation of a license are based have been corrected and after a proper inspection has been made, a new license may be granted.~~

#### **7.0 Regulations**

7.1 ~~The Division of Public Health may adopt, amend or repeal regulations governing the operation of Free Standing Emergency Centers and shall establish reasonable standards of equipment, capacity, sanitation and any other conditions which might influence the health or welfare of patients of such facilities.~~

#### **8.0 Penalties**

8.1 ~~Whoever operates a Free Standing Emergency Center in violation of these regulations shall be fined not less than \$100.00 nor more than \$1,000.00 for each offense. Every day such violation continues shall constitute a separate and distinct offense.~~

#### **9.0 Licensing Requirements and Procedures**

9.1 ~~When a facility is classified under this law and/or regulation and plans to construct, extensively remodel or convert any building, two (2) copies of properly prepared plans and specifications for the entire institution are to be submitted to the Division of Public Health. An approval, in writing, is to be obtained before such work is~~



begun. After the work is completed, in accordance with the plans and specifications, a new license to operate will be issued.

9.2 ~~Separate licenses are required for facilities maintained in separate locations, even though operated under the same management. A separate license is not required for separate buildings maintained by the same management on the same grounds. A license is not transferable from person to person nor from one location to another.~~

9.2.1 ~~In the event of the sale of a "Free Standing Emergency Center", the prospective buyer shall be informed of the waivers which were officially granted the previous owner. The Division of Public Health may grant the new owner the same waivers which had been granted to the former owner, with the condition that a plan for correcting all deficiencies within a reasonable time may be required to be submitted to and be acceptable to the Office Of Health Facilities Licensing And Certification prior to issuance of a license.~~

9.3 ~~The license shall be conspicuously posted.~~

9.4 ~~All applications for renewal of licenses shall be filed with the Division of Public Health at least thirty (30) days prior to expiration.~~

9.5 ~~All required records necessary to determine compliance with this regulation shall be open to inspection by the authorized representatives of the Division of Public Health.~~

9.6 ~~The terms emergency, urgent care or parts of those terms or any other language or symbols which imply or indicate to the public that immediate medical treatment is available to individuals suffering from a life threatening medical condition shall not be used as part of the name of any facility in this State, unless the facility has been licensed by the Division of Public Health.~~

9.7 ~~No rules shall be adopted by the licensee or administrator of any facility which are in conflict with these regulations.~~

9.8 ~~The Division of Public Health shall be notified, in writing within thirty (30) days of any changes in the administrator or director of the facility.~~

9.9 ~~The "Free Standing Emergency Center" must establish written policies regarding the rights and responsibilities of patients, and these policies and procedures are to be made available to patients, guardians, next of kin or sponsoring agency(ies).~~

9.10 ~~Each facility shall make available upon request to all patients or their sponsors, a complete statement enumerating all charges for service, materials and equipment which were furnished to the patient.~~

9.11 ~~Each facility shall conspicuously post the prepayment policy. In the event of third-party payment denial, a policy statement must be developed in writing and available upon request as to the responsibility for payment.~~

9.12 ~~A facility licensed under the provisions of this regulation as a "Free Standing Emergency Center", shall not refuse to render a needed, medically appropriate emergency service to any person because of that person's inability to pay for the service.~~

9.13 ~~Each facility shall coordinate with the office of Emergency Medical Services in regards to transfer agreements, communications requirements and disaster planning and preparedness.~~

9.14 ~~The Office of Emergency Medical Services and the Office of Narcotics and Dangerous Drugs shall be notified by the Office of Health Facilities Licensing and Certification of any proposal of licensing of Free Standing Emergency Centers.~~

## **10.0 Personnel**

### **10.1 Clinical Staff**

10.1.1 ~~The Free Standing Emergency Center shall have an organized clinical staff under the immediate and personal supervision of licensed physicians and nurses to provide emergency health care services 24 hours per day.~~

10.1.2 ~~At least one Licensed Nurse and Physician must be present in the facility at all times.~~

### **10.2 Clinical Staff Requirements**

10.2.1 ~~Each staff Physician shall be licensed to practice medicine in the State of Delaware and provide proof of licensure number.~~

10.2.2 ~~All staff Physicians must maintain current certification in Advanced Cardiac Life Support. (A Physician currently certified by American Board of Emergency Medicine needs no other certifications for delivery of emergency care.)~~

10.2.3 ~~Each staff nurse shall be licensed as a Professional Nurse in the State of Delaware and provide proof of license number.~~

10.2.4 ~~All members of the nursing team must maintain current certification in CPR.~~



- 10.2.5 ~~At least one member of the nursing team on duty must be currently certified in Advanced Cardiac Life Support.~~

#### **11.0 Medical Records**

- 11.1 ~~A medical record must be maintained on every patient seeking care in the Free Standing Emergency Center.~~
- 11.2 ~~The Free Standing Emergency Center shall provide sufficient space and equipment for the processing and safe storage of records.~~
- 11.3 ~~Medical records shall be protected from loss, damage and unauthorized use.~~
- 11.4 ~~Medical records of individuals eighteen years or older shall be preserved as original records or microfilm for no less than five (5) years after the most recent patient care usage, after which time records may be destroyed at the discretion of the facility. Medical records of minors (under the age of 18) shall be preserved for the period of minority plus five (5) years.~~
- 11.5 ~~The Facility shall establish procedures for destruction of Medical Records.~~
- 11.6 ~~Each time a patient visits the Free Standing Emergency Center the medical record shall contain sufficient accurate information. This information must include, but is not limited to:~~
- 11.6.1 ~~Complete patient identification and a unique identification number. When identification is not obtainable, the reason is entered in the medical record.~~
- 11.6.2 ~~Date, time and means of arrival and discharge.~~
- 11.6.3 ~~Pertinent history of the illness or injury and physical findings including the patient's vital signs.~~
- 11.6.4 ~~A complete description of emergency care given to the patient prior to arrival.~~
- 11.6.5 ~~A complete detailed description of treatment and procedures performed in the Free Standing Emergency Center.~~
- 11.6.6 ~~Clinical observations including the results of treatment.~~
- 11.6.7 ~~Reports of procedures, tests and results.~~
- 11.6.8 ~~Diagnostic impression.~~
- 11.6.9 ~~All medication and treatment orders signed by the prescribing physician.~~
- 11.6.10 ~~Conclusion at the termination of evaluation and/or treatment, including final disposition, the patient's condition on discharge or transfer and a copy of any instructions given to the patient and/or family for follow-up care.~~
- 11.7 ~~All orders for diagnostic procedures, treatments and medications shall be signed by the physician submitting them and entered in the medical record in ink or type. Authentication may be by written signature, identifiable initials or computer key. The use of rubber stamp signatures is acceptable under the following strict conditions:~~
- 11.7.1 ~~The physician whose signature the rubber stamp represents is the only one who has possession of the stamp and is the only one who uses it, and it may not be used for controlled substances.~~
- 11.7.2 ~~The physician places in the administrative office of the facility, a signed statement to the effect that he/she is the only one who has the stamp and is the only one who will use it.~~
- 11.8 ~~Standard nursing practice and procedure shall be followed in the recording of medications and treatments including treatment notes. Nursing notes shall include notation of the instructions given patients at the time of discharge. All recordings shall be in ink and properly signed including name and identifying title.~~
- 11.9 ~~The facility shall also maintain the following:~~
- 11.9.1 ~~A log of all patients presenting for treatment performed and entered daily.~~
- 11.9.2 ~~Statistical information concerning all admissions, discharges, deaths and other information such as blood usage, treatment complications, etc. required for the effective administration of the facility.~~
- 11.9.3 ~~Master patient index file.~~

#### **12.0 Medications**

- 12.1 ~~Medication must be purchased, stored, administered and dispensed in compliance with applicable State and Federal Statutes and Regulations. Those requirements include, but are not limited to the following:~~
- 12.2 ~~The site must be properly registered under the *State and Federal Controlled Substances Acts*. Any time a change in policy is made it should be dated.~~
- 12.3 ~~A policy and procedure manual must be established and approved by the Governing Board.~~
- 12.3.1 ~~It shall be reviewed annually.~~
- 12.3.2 ~~Any additions or deletions should show an effective date.~~



- 12.3.3 It shall contain automatic stop orders, labeling requirements, discontinued medication policy, drug storage policy, charting policy, medication error policy, drug recall policy, prescriber medication order procedure, out dated medication procedures.
- 12.4 Standing orders shall be written and administered in compliance with the regulation of the Board of Medical Practice.
- 12.5 Verbal orders must be countersigned by the prescriber within 72 hours of receipt.
- 12.6 Rubber stamp signatures are not acceptable for controlled substances orders.
- 12.7 All records concerning controlled substances must be retained for a period of two (2) years from the last entry. It must show the date of administration or dispensing, the time, the name, strength and quantity of the drug involved, the name of the patient and the initials of the person removing the medication. The same information concerning the receipt of medication must be documented.
- 12.8 Medications shall be properly secured in locked areas only accessible to authorized persons.
  - 12.8.1 Schedule II medications shall be under double lock.
- 12.9 Medication must be stored according to the latest USP/NF standards.
  - 12.9.1 Room temperature 59 to 86 degrees Fahrenheit; refrigerator 36 to 46 degrees Fahrenheit.
- 12.10 Internal medications shall be stored separately from external medications.
- 12.11 All medications shall be accurately and plainly labeled:
  - 12.11.1 Dispensed medications shall be labeled in compliance with 24 **Del. C.** §2563.
  - 12.11.2 Prepaks must be labeled in compliance with Board of Pharmacy Regulation.
- 12.13 All medications on site or dispensed must be in packaging which complies with the latest edition of USP/NF.
- 12.14 Medication discontinued must be properly documented on the patient's chart or other applicable record.
  - 12.14.1 Controlled substance documentation should contain two signatures.
- 12.15 Only a physician or pharmacist may dispense medications.
  - 12.15.1 Nurses may assist the physician with dispensing provided the physician directly supervises that person (24 **Del. C.** §2521).
- 12.16 Only licensed nurses and physicians may administer medications.
- 12.17 Stock supplies of controlled drugs can only be destroyed via procedures established by ONDD or DEA.
- 12.18 Syringes must be stored and destroyed in compliance with 16 **Del. C.** §4757, State CSA Regulation 5.

### **13.0 Infection Control**

- 13.1 Prevention and Control Services
  - 13.1.1 The facility shall establish and implement an infection control program. The chief executive officer shall ensure the development and implementation of the program.
  - 13.1.2 The facility shall establish and implement written policies and procedures regarding infection prevention and control, for patients and employees including, but not limited to the following:
    - 13.1.2.1 A system for investigating, reporting and evaluating the occurrence of all infections or diseases which are reportable or conditions which may be related to activities and procedures of the facility and maintaining records for all patients or personnel having these infections, diseases or conditions.
    - 13.1.2.2 Reportable diseases shall be reported to the Director of the Division of Public Health.
    - 13.1.2.3 Care of patients with communicable diseases.
    - 13.1.2.4 Policies and procedures for exclusion from work and authorization to return to work for personnel with communicable diseases.
    - 13.1.2.5 Surveillance techniques to minimize sources and transmission of infection.
    - 13.1.2.6 Sterilization, disinfection and cleaning practices and techniques used in the facility including, but not limited to the following:
      - 13.1.2.6.1 Care of utensils, instruments, solutions, dressings, articles and surfaces.
      - 13.1.2.6.2 Selection, storage, use and disposition of disposable and non-disposable patient care items. Disposable items shall not be reused; dialyzer may be reused by facilities providing chronic dialysis services.
      - 13.1.2.6.3 Methods to ensure that sterilized materials are packaged and labeled to maintain sterility and to permit identification of expiration dates.
      - 13.1.2.6.4 Procedures for care of equipment and other devices that provide a portal of entry for pathogenic micro-organisms.



~~13.1.2.6.5 Techniques to be used during each patient contact, including handwashing before and after caring for a patient.~~

~~13.1.2.6.6 Criteria and procedures for isolation of patients.~~

~~13.1.2.7 Each service in the facility shall develop written infection control policies and procedures for that service.~~

~~13.1.2.8 All personnel shall receive orientation at the time of employment and continuing inservice education regarding the infection prevention and control program.~~

#### ~~13.2 Infectious Disease and Waste Removal~~

~~13.2.1 The facility shall establish and implement policies and procedures for the collection, storage, handling and disposition of all pathological and infectious wastes within the facility, and for the collection, storage, handling and disposition of all pathological and infectious wastes to be removed from the facility, including, but not limited to the following:~~

~~13.2.1.1 Needles and syringes shall be destroyed or disposed of in a safe and proper manner.~~

~~13.2.1.2 Needles and syringes and other solid, sharp or rigid items shall be placed in a puncture resistive container and incinerated or compacted prior to disposal.~~

~~13.2.1.3 Non-rigid items, such as blood tubing and disposable equipment and supplies, shall be incinerated or placed in double, heavy duty, impervious plastic bags and disposed.~~

~~13.2.1.4 Fecal matter and liquid waste, such as blood and blood products, shall be flushed into the sewerage system.~~

~~13.2.1.5 All pathology specimens and waste, including gross and microscopic tissue removed surgically or by any other procedure, shall be incinerated.~~

~~13.2.1.6 Solid waste from the laboratory shall be incinerated or autoclave prior to disposal.~~

~~13.2.1.7 Liquid waste from the laboratory shall be autoclave prior to disposal into the sewerage system.~~

#### **14.0 Equipment and Supplies**

~~14.1 There shall be appropriate equipment and supplies maintained for the Free Standing Emergency Center to include, but not limited to:~~

~~14.1.1 Immediately available oxygen with flow meters and masks or equivalent.~~

~~14.1.2 Immediately available mechanical suction.~~

~~14.1.3 Airway maintenance and resuscitation equipment to include resuscitation bags, laryngoscopies and blades of varying sizes and shapes, endotracheal tubes, cricothyrotomy tubes and adapters. Ventilation devices must be capable of delivering 1000 oxygen.~~

~~14.1.4 Spine immobilization equipment to include sandbags and/or semi-rigid collars.~~

~~14.1.5 Complete intravenous infusion sets and standards with a reserved supply of at least six liters PSS or RL.~~

~~14.1.6 Cardiac monitors and defibrillators together with an effective cardiac pacing system.~~

~~14.1.7 Equipment and supplies needed to empty and drain stomachs and bladders.~~

~~14.1.8 Newborn and pediatric resuscitation equipment.~~

~~14.1.9 Sterile suturing equipment and supplies.~~

#### **15.0 Plant, Equipment & Physical Environment**

~~15.1 Site Provisions:~~

~~15.1.1 Each institution shall be located on a site which is considered suitable by the Division of Public Health. Site must be easily drained, must be suitable for disposal of sewage and furnishing a potable water supply.~~

~~15.2 Water Supply and Sewage Disposal:~~

~~15.2.1 The water supply and the sewage disposal system shall be approved by the Division of Public Health and the Department of Natural Resources and Environmental Control respectively.~~

~~15.2.2 The water system shall be designed to supply adequate hot and cold water, under pressure, at all times.~~

~~15.3 Building:~~

~~15.3.1 All new construction, extensive remodeling or conversions shall comply with the standards set forth under the "Free Standing Emergency Facility" section of the current or subsequent editions of "General Standards of Construction and Equipment for Hospitals and Medical Facilities", a publication of the U.S. Department of Health and Human Services.~~

~~15.3.2 Each facility shall provide the following:~~



- 15.3.2.1 Entrance and driveway shall be clearly marked. If platform is provided for ambulance use, a ramp for pedestrian and wheelchair access must be provided.
- 15.3.2.2 Reception and control station shall be located to permit staff observation and control of access to treatment area, pedestrian and ambulance entrances and public waiting area.
- 15.3.2.3 Wheelchair and stretcher storage shall be provided for arriving patients. This shall be out of traffic with convenient access from emergency entrances.
- 15.3.2.4 Public waiting area with toilet facilities, drinking fountains and telephones shall be provided.
- 15.3.2.5 Each treatment /examination room(s) shall have at least 7.43 square meters (80 square feet) of clear floor space and shall contain work counter(s), cabinets, hand wash facilities and have access to x-ray film illuminators and examination lights.
- 15.3.2.6 If the facility provides trauma services, trauma room(s) for emergency trauma procedure, including emergency surgery shall have at least 13.37 square meters (144 square feet) of clear floor space. Each room shall have cabinets and emergency supply shelves, and have access to x-ray film illuminators, and examination lights. Additional space with cubicle curtains for privacy may be provided to accommodate more than one patient at a time in the trauma room.
- 15.3.2.7 Orthopedic and cast work may be in separate room(s) or in the trauma room. They shall include storage for splints and other orthopedic supplies, a plaster sink and have access to x-ray film illuminators and examination lights.
- 15.3.2.8 Adequate hand washing facilities convenient to each treatment area shall be provided.
- 15.3.2.9 Convenient on-site access to radiology and laboratory service.
- 15.3.2.10 Provide for poison control with immediate access to antidotes and file of common poisons as well as provisions for communication with regional and/or national poison centers. This may be part of the nurses' control and work station.
- 15.3.2.11 Provisions for disposal of solid and liquid waste. This may be a clinical sink with bedpan flushing device within the soiled workroom.
- 15.3.2.12 Storage area for "crash cart", and other equipment located out of traffic and easily accessible to each trauma and treatment room.
- 15.3.2.13 Toilet room for patients and staff.
- 15.3.2.14 Storage rooms for clean and soiled or used supplies. Soiled and clean rooms shall be separated without direct connection.
- 15.3.2.15 Staff work and charting area station with counters, cabinets and medication storage. This area may be combined with, or include, centers for reception control, poison control and communication. Provide for convenient access to handwashing facilities.

#### 15.4 Plumbing

- 15.4.1 The plumbing shall meet the requirements of all municipal, country or state codes. Where there are no local codes, the provisions of the Division of Public Health regulations governing a detailed plumbing code shall prevail.

#### 15.5 Heating/Air Conditioning

- 15.5.1 The heating and air conditioning equipment for all sections of the building shall be adequate, safe, protected and easily controlled. It shall be capable of maintaining the temperature in each room at a minimum of 72 degrees F. (21 degrees C) and not to exceed 81 degrees F. Portable heating equipment is strictly prohibited.

#### 15.6 Lighting:

- 15.6.1 Each room must be suitably lighted at all times for maximum safety, comfort, sanitation and efficiency of operation. This includes hallways, stairways, storerooms and bathrooms.
- 15.6.2 An alternate emergency power source to sustain lighting must be provided.

#### 15.7 Electrical:

- 15.7.1 All electrical requirements shall be in compliance with all municipal or county codes.

#### 15.8 Mechanical Equipment

- 15.8.1 Mechanical equipment shall be kept in working order at all times.

#### 15.9 Pest Control

- 15.9.1 The building shall be so constructed and maintained to prevent the entrance or existence of rodents and insects at all times.

#### 15.10 Sanitation and Housekeeping.



15.10.1 ~~A secured ventilated janitor's closet shall be provided for each floor. This closet will contain a service floor/level sink, hot and cold water and mixing faucet.~~

15.10.2 ~~Linen Services:~~

15.10.2.1 ~~On Site Processing Requirements: The laundry shall include: One room with separate areas for receiving, sorting and washing of soiled linen; one room for drying, mending and storing of clean linen; and handwashing facilities immediately accessible to both the preceding areas.~~

15.10.2.2 ~~Off Site Processing Requirements: Laundry that is sent out shall be sent to a commercial or hospital laundry. A contract for laundry services performed by commercial laundries shall meet all local and state regulations.~~

15.10.2.2.1 ~~If soiled linen is not processed on a daily basis, a separate, properly ventilated storage area shall be provided.~~

15.10.2.2.2 ~~The linens to be returned from the outside laundry to the facility shall be completely wrapped or covered to protect against contamination.~~

15.10.2.2.3 ~~Clean Linen Storage Area: Adequate provisions shall be made for storage of clean linen.~~

15.10.2.3 ~~There shall be a reasonable amount of clean linen available at all times.~~

15.10.3 ~~All rooms and every part of the building shall be kept clean, safe, orderly and free of offensive odors.~~

## **16.0 Fire Safety**

16.1 ~~Fire Safety in a Free Standing Emergency Center shall comply with the adopted rules and regulations of the State Fire Prevention Commission. Enforcement of the State Fire Regulations is the responsibility of the State Fire Prevention Commission. All applications for license or renewal of license must include, with the application, a letter certifying compliance by the Fire Marshal having jurisdiction. Notification of non-compliance with the Rules and Regulations of the State Fire Prevention Commission shall be grounds for revocation of license.~~

16.2 ~~Accident Prevention:~~

16.2.1 ~~There shall be a written evacuation and fire plan for the removal of patients in case of fire and other emergencies. The plan shall be posted in a conspicuous place in the building.~~

16.2.2 ~~A simulated drill shall be performed every quarter per work shift. A written record of each drill shall be kept on file.~~

## **17.0 Severability**

17.1 ~~Should any section, sentence, clause or phrase of these regulations be legally declared unconstitutional or invalid for any reason, the remainder of said regulations shall not be thereby affected.~~

## **1.0 Purpose**

Delaware Department of Health and Social Services adopts these regulations pursuant to the authority vested by 16 Del.C. §122(3)p.

## **2.0 Definitions**

The following words and terms, when used in this regulation, have the following meaning unless the context clearly indicates otherwise:

"Abuse" means the infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain, or mental anguish and includes all of the following:

a. Physical abuse. — "Physical abuse" means the unnecessary infliction of pain or injury to a patient or resident. "Physical abuse" includes hitting, kicking, punching, slapping, or pulling hair. If any act constituting physical abuse has been proven, the infliction of pain is presumed.

b. Sexual abuse. — "Sexual abuse" includes any sexual contact, sexual penetration, or sexual intercourse, as those terms are defined in §761 of Title 11, with a patient or resident by an employee or volunteer working at a facility. It is not a defense that the sexual contact, sexual penetration, or sexual intercourse was consensual.

c. Emotional abuse. — "Emotional abuse" means the use of oral, written, or gestured language that includes disparaging and derogatory terms to patients, residents, their families, or within their hearing distance, regardless of their age, ability to comprehend, or disability. "Emotional abuse" includes the violation of resident rights and privacy through the posting of inappropriate materials on social media.



"Emotional abuse" includes all of the following: ridiculing, demeaning, humiliating, or cursing at a patient or resident; punishment or deprivation; or threatening a patient or resident with physical harm.

- d. 1. Medication diversion. — **"Medication diversion"** means the knowing or intentional interruption, obstruction, or alteration of the delivery, or administration of a prescription drug to a patient or resident, if both of the following apply:
- A. The prescription drug was prescribed or ordered by a licensed independent practitioner for the patient or resident.
  - B. The interruption, obstruction, or alteration occurred without the prescription or order of a licensed independent practitioner.
2. "Medication diversion" does not mean conduct performed by any of the following:
- A. A licensed independent practitioner or licensed health-care professional who acted in good faith within the scope of the individual's practice or employment.
  - B. An individual acting in good faith while rendering emergency care at the scene of an emergency or accident.

**"Adverse Incident"** means an event that results in unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient.

**"Clinical Director"** means a registered nurse, currently licensed to practice nursing pursuant to Title 24, Chapter 19 of the Delaware Code who is sufficiently qualified to provide general supervision and direction of the services offered by the FSED.

**"Department"** means the Delaware Department of Health and Social Services.

**"Director"** means a full-time physician who is board certified in emergency medicine.

**"Emergency Care"** means services provided in a free standing emergency department on an outpatient basis for medical conditions that include those manifested by symptoms of sufficient severity that, in the absence of immediate medical attention, could result in (1) placing the patient's health in jeopardy, (2) serious impairment to bodily functions, (3) serious dysfunction of any bodily organ or part, or (4) development or continuance of severe pain.

**"Exploitation"** means the illegal or improper use of a patient's resources or financial rights by another person, whether for profit or other advantage.

**"Facility"** means a free standing emergency department.

**"Free Standing Emergency Department" or "FSED"** means a facility, physically separate from a hospital, which is established, maintained and operated twenty-four (24) hours per day, seven (7) days per week for the purpose of providing immediate and emergency care to individuals suffering from a life-threatening medical condition. A free standing emergency department that is owned and operated by a hospital and deemed by an accreditation organization approved by the Centers for Medicare and Medicaid Services is exempt from licensure and this set of regulations.

**"Governing Body"** means the individual, group or corporation appointed, elected, or otherwise designated, in which the ultimate responsibility and authority for the conduct of the FSED is vested.

**"Hospital"** means a facility currently licensed as a hospital pursuant to Title 16, Chapter 10 of the Delaware Code.

**"Incident"** means a circumstance or occurrence that may be injurious to a patient or that may result in an adverse outcome to the patient.

**"Medical Staff"** means a physician or non-physician provider who by action of the FSED's governing body are privileged to work in and use the facility.

**"Modification of Ownership and Control"** means a change of ownership or transfer of responsibility for the FSED's operation.

**"Neglect"** means the failure to provide goods or services that are necessary to avoid adversely affecting the physical, mental, or emotional welfare of the patient.

**"Non-physician Provider"** means a person currently licensed as an advanced practice nurse pursuant to Title 24, Chapter 17 of the Delaware Code, or a person currently licensed as a physician's assistant pursuant to Title 24, Chapter 19 of the Delaware Code.

**"Patient"** means a person who receives health care services from a FSED.

**"Physician"** means a person currently licensed as a physician by Title 24, Chapter 17 of the Delaware Code.

**"Plan of Correction"** means a written document that includes specific measures to correct identified problems or areas of concern; identifies strategies for implementing system improvements; and includes outcome measures to indicate the effectiveness of system improvements in reducing, controlling or eliminating identified problem areas.



**“Quality Assessment and Performance Improvement” or “QAPI”** means an ongoing program that measures, analyzes, and tracks quality indicators related to improving health outcomes and patient care emphasizing a multidisciplinary approach. The program implements plans and evaluates the implementation until resolution is achieved.

**“Registered Nurse”** means a person currently licensed as a registered nurse pursuant to Title 24, Chapter 19 of the Delaware Code.

**“Regulated Waste”** means liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.

**“Renovation”** means 1) the strengthening or upgrading of building elements, materials, equipment, or fixtures that does not result in a reconfiguration of the building spaces within; or 2) any reconfiguration of a space that affects an exit, a corridor, or any component of a means of egress; or 3) work that changes the current designated purpose or occupancy classification of a building space. Cosmetic changes such as repainting or changing carpeting are not considered renovations.

**“Resident Physician”** means a person who currently holds physician training licensure by Title 24, Chapter 17 of the Delaware Code.

**“Serious Injury”** means physical injury that creates a substantial risk of death, or that causes serious disfigurement, prolonged impairment of health or prolonged loss or impairment of the function of any bodily organ.

**“Stabilization”** means to provide necessary medical treatment of an emergency medical condition to ensure, within reasonable medical probability, that the condition is not likely to deteriorate materially from or during the transfer of the individual from the facility.

**“Substantial Compliance”** means a level of compliance with the requirements such that any identified deficiencies pose no greater risk to patient health or safety than the potential for causing minimal harm.

**“Unethical Conduct”** means conduct prohibited by ethical standards adopted by state or national professional organizations for their respective professions or by rules adopted by the state licensing agency for the respective profession.

**“Unprofessional Conduct”** means conduct prohibited under rules adopted by the state licensing agency for the respective profession.

### **3.0   Licensure Requirements and Procedures**

#### **3.1   General Requirements**

- 3.1.1**   No person shall establish, conduct or maintain in this State any FSED without first obtaining a license from the Department.
- 3.1.2**   No FSED, treatment facility, office or station shall be authorized to exhibit any emergency trailblazing signs, symbols or directional signs by the Delaware Department of Transportation unless such facility has been duly licensed under the provisions of these regulations.
- 3.1.3**   A license is not transferable from person to person, entity to entity or from one location to another.
- 3.1.4**   The license shall be posted in a conspicuous place on the licensed premises, at or near the entrance in a manner which is plainly visible and easily read by the public.
- 3.1.5**   Separate licenses are required for FSEDs maintained in separate locations, even though operated under the same management.
- 3.1.6**   Any FSED that undergoes a modification of ownership and control is required to re-apply as a new FSED and must meet the current design and construction standards recognized by the Department.
- 3.1.7**   The submission of an application is in no way a guarantee that the completed application will be accepted or that a license will be issued by the Department.
- 3.1.8**   Patients shall not be admitted to a FSED until a license has been issued.
- 3.1.9**   The FSED shall advise the Department in writing at least 30 calendar days prior to closure of the FSED and voluntary surrender of a license.

#### **3.2   Application Process**

- 3.2.1**   All persons or entities wanting to apply to open a FSED shall submit to the Department the following information:
  - 3.2.1.1**   A Statement of Intent describing the services to be offered at the FSED;
  - 3.2.1.2**   A completed application for licensure;



- 3.2.1.3 The names, addresses and types of facilities previously and currently owned or managed by the applicant;
- 3.2.1.4 Identity of:
  - 3.2.1.4.1 Each officer and director of the corporation, if the entity is organized as a corporation;
  - 3.2.1.4.2 Each general partner or managing member, if the entity is organized as an unincorporated entity;
  - 3.2.1.4.3 The governing body; and
  - 3.2.1.4.4 Any officers/directors, partners, or managing members, or members of a governing body who have a financial interest in a licensee's operation or related business.
- 3.2.1.5 Proof of not-for-profit status, if claiming tax-exempt status;
- 3.2.1.6 Disclosure of any officer, director, partner, employee, managing member or member of the governing body with a felony criminal record;
- 3.2.1.7 Name of the director and the person designated to act in the absence of the director;
- 3.2.1.8 A list of management personnel, including credentials;
- 3.2.1.9 A plan for providing orientation, continuing education, and training for personnel or independent contractors during the first year of operation;
- 3.2.1.10 Policy and procedure manuals; and
- 3.2.1.11 Any other information required by the Department.

### 3.3 Issuance of Licenses

#### 3.3.1 Initial License

- 3.3.1.1 An initial license shall be granted for a period of three (3) calendar months to every FSED that completes the application process consistent with those regulations and whose policies and procedures demonstrate compliance with the rules and regulations pertaining to FSED licensure.
- 3.3.1.2 An initial license will permit a FSED to hire or contract with personnel and begin to offer services.
- 3.3.1.3 All FSED shall have an on-site survey, conducted by the Department, during the first three (3) calendar months of operation.
- 3.3.1.4 A FSED at the time of an initial on-site survey, must meet the definition of a free standing emergency department as contained within these regulations and must be in operation and caring for patients. Facilities that, at the time of the onsite survey, do not meet the definition of a FSED or that are not in substantial compliance with these regulations will not be granted an annual license.
- 3.3.1.5 An initial license may not be renewed.

#### 3.3.2 Provisional License

- 3.3.2.1 A provisional license shall be granted, for a period of less than one year, to all FSEDs that:
  - 3.3.2.1.1 Are not in substantial compliance with these rules and regulations; or
  - 3.3.2.1.2 Fail to renew a license within the timeframe prescribed by these regulations.
- 3.3.2.2 Upon issuance of a provisional license, the Department shall designate the conditions and the time period in writing.
- 3.3.2.3 A provisional license may not be renewed unless a Plan of Correction for coming into substantial compliance with these rules and regulations has been approved by the Department and implemented by the FSED.
- 3.3.2.4 A license will not be granted after the provisional licensure period to any FSED that is not in substantial compliance with these rules and regulations.

#### 3.3.3 Annual License

- 3.3.3.1 An annual license shall be effective for a twelve (12) month period following the date of issue and shall expire one year following such date, unless it is modified, suspended, revoked or surrendered prior to the expiration date.
- 3.3.3.2 All applications for renewal of licenses must be filed with the Department at least thirty (30) days prior to the expiration date of the license.
- 3.3.3.3 FSEDs which have not been inspected/surveyed during a licensure year may apply for, and be issued, a new license until an inspection/survey is completed.
- 3.3.3.4 An annual license may not be issued to a FSED which is not in substantial compliance with these regulations or whose deficient practices present an immediate threat to the health and safety of its patients.



- 3.4 The Department may deny a licensure renewal or suspend or revoke a license issued under these regulations on any of the following grounds:
- 3.4.1 Violation of any of the provisions of 16 Del.C. §122(3)p or these regulations.
- 3.4.2 Permitting, aiding or abetting the commission of any illegal act in the facility.
- 3.4.3 Conducts or practices detrimental to the welfare of a patient.
- 3.4.4 Imposition of a disciplinary action.
- 3.4.4.1 The Department shall give 20 calendar days written notice to the holder of the license, setting forth the reasons for the determination;
- 3.4.4.2 The disciplinary action shall become final 20 calendar days after the mailing of the notice unless the licensee, within such 20-calender-day period, shall give written notice of the FSED desire for a hearing;
- 3.4.4.3 If the licensee gives such notice, the FSED shall be given a hearing before the Secretary of the Department or the Secretary's designee and may present such evidence as may be proper;
- 3.4.4.4 The Secretary of the Department or the Secretary's designee shall make a determination based upon the evidence presented.
- 3.4.4.5 A written copy of the determination and the reasons upon which it is based shall be sent to the FSED;
- 3.4.4.6 The decision shall become final 20 calendar days after the mailing of the determination letter unless the licensee, within the 20-calender-day period, appeals the decision to the appropriate court of the State
- 3.5 Order to immediately suspend a license.
- 3.5.1 In the event the Department identifies activities which the Department determines present an immediate jeopardy or imminent danger to the public health, welfare and safety requiring emergency action, the Department may issue an order temporarily suspending the licensee's license, pending a final hearing on the complaint. No order temporarily suspending a license shall be issued by the Department, with less than 24 hours prior written or oral notice to the licensee or the licensee's attorney so that the licensee may be heard in opposition to the proposed suspension. An order of temporary suspension under this section shall remain in effect for a period not longer than 60 calendar days from the date of the issuance of said order, unless the suspended licensee requests a continuance of the date for the final hearing before the Department. If a continuance is requested, the order of temporary suspension shall remain in effect until the Department has rendered a decision after the final hearing.
- 3.5.2 The licensee, whose license has been temporarily suspended, shall be notified forthwith in writing. Notification shall consist of a copy of the deficiency report and the order of temporary suspension pending a hearing and shall be personally served upon the licensee or sent by mail, return receipt requested, to the licensee's last known address.
- 3.5.3 A licensee whose license has been temporarily suspended pursuant to this section may request an expedited hearing. The Department shall schedule the hearing on an expedited basis provided that the Department receives the licensee's written request for an expedited hearing within 5 calendar days from the date on which the licensee received notification of the Department's decision to temporarily suspend the licensee's license.
- 3.5.4 As soon as possible, but in no event later than 60 calendar days after the issuance of the order of temporary suspension, the Department shall convene a hearing on the reasons for suspension. In the event that a licensee, in a timely manner, requests an expedited hearing, the Department shall convene within 15 calendar days of the receipt by the Department of such a request and shall render a decision within 30 calendar days.
- 3.5.5 In no event shall an order of temporary suspension remain in effect for longer than 60 calendar days unless the suspended licensee requests an extension of the order of temporary suspension pending a final decision of the Department. Upon a final decision of the Department, the order of temporary suspension may be vacated in favor of the disciplinary action ordered by the Department.
- 3.6 Renewal of License After Suspension or Revocation
- 3.6.1 If and when the conditions upon which the suspension or revocation of a license are based have been corrected and after a proper inspection has been made, a new license may be granted.
- 3.7 Modification of Ownership and Control (MOC)
- 3.7.1 Any proposed MOC must be reported to the Department in writing a minimum of 30 calendar days prior to the change.



- 3.7.2 A MOC occurs whenever the ultimate legal authority for the responsibility of the FSED's operation is transferred.
- 3.7.3 A MOC voids the current license in possession of the FSED.
- 3.7.4 A MOC will be treated as an initial license and the FSED must meet the current design and construction standards recognized by the Department.
- 3.7.5 A MOC may include but is not limited to:
  - 3.7.5.1 Transfer of the FSED's legal title;
  - 3.7.5.2 Transfer of the full ownership rights;
  - 3.7.5.3 Transfer of the majority interest;
  - 3.7.5.4 Transfer of ownership interest that results in the owner with the majority interest becoming a minority interest owner;
  - 3.7.5.5 Transfer or re-organization that results in an additional majority interest that is equal in ownership rights;
  - 3.7.5.6 Transfer resulting in a measurable impact upon the operational control of the FSED;
  - 3.7.5.7 Dissolution of any partnership that owns, or owns a controlling interest in the FSED;
  - 3.7.5.8 Merger of a FSED owner (a corporation) into another corporation where, after the merger, the owner's shares of capitol stock are cancelled; or
  - 3.7.5.9 The consolidation of a corporate FSED owner with one or more corporations;
- 3.7.6 Transactions which do not constitute an MOC include, but are not limited to the following:
  - 3.7.6.1 Changes in the membership of a corporate board of directors or board of trustees;
  - 3.7.6.2 Two or more corporations merge and the originally licensed corporation survives;
  - 3.7.6.3 Changes in the membership of a non-profit corporation; or
  - 3.7.6.4 Corporate stock transfers or sales that do not result in a transfer of interest or ownership.
- 3.7.7 Applications for licensure, as a result of an MOC must include a description of:
  - 3.7.7.1 Any actual or anticipated change in the health care services provided before the MOC;
  - 3.7.7.2 Any actual or anticipated change in staff, including the composition of staff;
  - 3.7.7.3 Any actual or anticipated change in the policies and procedures; and
  - 3.7.7.4 Any change in the manner of delivery of health care services.
- 3.8 Fees. Fees shall be in accordance with 16 Del.C. §122(3)p.
- 3.9 Inspection. A representative of the Department shall periodically inspect every FSED for which a license has been issued under these regulations. Inspections by authorized representatives of the Department may occur at any time and may be scheduled or unannounced.
- 3.10 Whoever operates a FSED in violation of these regulations shall be fined not less than \$100.00 nor more than \$1000.00 for each offense. Every day such violation continues shall constitute a separate and distinct offense.

#### **4.0 General Requirements**

- 4.1 When a facility is classified under this law or regulation and plans to construct or renovate any building, one (1) copy of properly prepared plans and specifications for the entire FSED are to be submitted to the Department. An approval, in writing, is to be obtained before such work is begun.
- 4.2 All records maintained by the FSED shall be open to inspection by authorized representatives of the Department.
- 4.3 The FSED must permit photocopying of any records or other information by, or on behalf of authorized representatives of the Department, as necessary to determine or verify compliance with these regulations.
- 4.4 The term "emergency" or symbols which imply or indicate to the public that emergency medical treatment is available to individuals suffering from a life threatening medical condition shall not be used as part of the name of any facility in this State, unless the facility has been licensed by the Department as a FSED or hospital.
- 4.5 No policies shall be adopted by the licensee or FSED which are in conflict with these regulations.
- 4.6 The Department shall be notified, in writing within thirty (30) days of any changes in the director or clinical director of the facility.
- 4.7 The FSED must establish written policies regarding the rights and responsibilities of patients, and these policies and procedures are to be made available to patients, guardians, next of kin or sponsoring agency or agencies.
- 4.8 Each facility shall make available upon request to all patients or their representative, a complete statement enumerating all charges for service, materials and equipment which were furnished to the patient.



- 4.9 Each facility shall conspicuously post the prepayment policy. In the event of third-party payment denial, a policy statement must be developed in writing and available upon request as to the responsibility for payment.
- 4.10 A facility licensed under the provisions of this regulation as a "Free Standing Emergency Department", shall not refuse to render a needed, medically appropriate emergency service to any person.
- 4.11 A facility licensed as a FSED shall maintain the services, staff, equipment and drugs necessary to provide an appropriate medical screening evaluation and stabilization of a patient of any age who presents at the facility.
- 4.12 Each facility shall coordinate with the Office of Emergency Medical Services in regards to transfer agreements, communications requirements and disaster planning and preparedness.
- 4.13 The Office of Emergency Medical Services and the Office of Narcotics and Dangerous Drugs shall be notified by the Office of Health Facilities Licensing and Certification of any proposal of licensing of FSEDs.
- 4.14 The FSED must have a written transfer agreement, including a plan for transportation, in effect with one or more general acute care hospitals that provide basic or comprehensive emergency medical services wherein patients requiring more definitive care will be expeditiously transferred to receive prompt hospital care.
- 4.15 The FSED shall be in compliance with federal, state and local laws and codes.
- 4.16 The provisions of the Centers for Disease Control and Prevention Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005, are hereby adopted as the regulatory requirements for FSEDs in Delaware and are hereby referred to, and made part of this Regulation, as if fully set out herein.
- 4.17 The provisions of the 2018 Facility Guidelines Institute's Guidelines for Design and Construction of Health Care Facilities, are hereby adopted as the regulatory requirements for FSEDs in Delaware and are hereby referred to, and made part of this Regulation, as if fully set out herein.
- 4.17.1 When a FSED is classified under this law or regulation and plans to construct or renovate any buildings, one (1) copy of the properly prepared plans and specifications for the entire FSED shall be submitted to the Department.
- 4.17.2 An approval, in writing shall be obtained from the Department before construction/renovation work is begun.
- 4.17.3 Upon completion of construction/renovation, in accordance with the plans and specifications, the Department will inspect and approve the site prior to occupancy/use by the FSED.
- 4.17.4 All facilities shall either be at grade level or shall be equipped with ramps and elevators to allow easy access for persons with disabilities.
- 4.17.5 The FSED shall comply with all local and state building codes and ordinances as pertains to this occupancy.
- 4.17.6 Waiver of a standard requires Department approval. Waiver requests must be made in writing, include the full justification behind the request and address issues of safety and infection control. Waivers are an exception to established standards and will only be approved for compelling reason.
- 4.18 The provisions of the State of Delaware Food Code, 16 **DE Admin. Code** 4458, are hereby adopted as the regulatory requirements for FSEDs in Delaware and are hereby referred to, and made part of this Regulation, as if fully set out herein.
- 4.19 The FSED may contract for services to be provided to its patients. Individuals providing services under contract must meet the same requirements as those persons employed directly by the FSED.
- 4.20 Major Adverse Incidents
- 4.20.1 A major adverse incident includes but is not limited to:
- 4.20.1.1 Suspected abuse, neglect, mistreatment, exploitation, solicitation or harassment of patients;
- 4.20.1.2 An accident that causes serious injury to a patient;
- 4.20.1.3 A medication error with the potential to result in adverse health outcomes for the patient;
- 4.20.1.4 The unexpected death of a patient while under care of the facility;
- 4.20.1.5 A patient stay exceeding 23 hours; and
- 4.20.1.6 Activation of 9-1-1.
- 4.20.2 Reports of major adverse incidents shall be kept on file at the FSED for a minimum of five (5) years.
- 4.20.3 The FSED must report all major adverse incidents to the Department within 48 hours in addition to other reporting requirements required by law.
- 4.20.4 Major adverse incidents must be investigated by the FSED.
- 4.20.5 The FSED must submit a complete investigation report to the Department within 30 calendar days of the incident.



- 4.21 The FSED shall participate in the Delaware Health Information Network as data senders and end users.
- 4.22 To receive emergency medical services patients, the FSED must comply with the requirements and procedures for medical command facility designation set forth by the Division of Public Health's Office of Emergency Medical Services.
- 4.23 The provisions of the Americans with Disabilities Act of 1990 are hereby adopted as the regulatory requirements for FSEDs in Delaware and are hereby referred to, and made part of this Regulation, as if fully set out herein.
- 4.24 The provisions of Section 504 of the Rehabilitation Act of 1973. are hereby adopted as the regulatory requirements for FSEDs in Delaware and are hereby referred to, and made part of this Regulation, as if fully set out herein.

## **5.0 Governing Body**

- 5.1 Each FSED shall have an identified, organized governing body (governing authority, owner or person or persons designated by the owner) fully responsible for the organization, management, control, and operation of the facility.
- 5.2 The governing body responsibilities include:
  - 5.2.1 Appointing a qualified director in writing;
  - 5.2.2 Appointing members of the medical and clinical staff, ensuring their competence and delineating their job responsibilities;
  - 5.2.3 Adopting, implementing, and enforcing written policies and procedures for the total operation and all services provided by the facility;
  - 5.2.4 Documentation of annual review and evaluation of the FSED policies and services;
  - 5.2.5 All services furnished by the facility, whether furnished directly or under contract are provided in a safe and effective manner that permits the facility to comply with all applicable rules and standards;
  - 5.2.6 Conducting meetings, when the governing body is more than one person, at least annually and maintaining written minutes of the meetings;
  - 5.2.7 Adopting governing body and medical staff bylaws for the orderly development and management of the FSED.
    - 5.2.7.1 Bylaws shall be reviewed annually by the governing body and so dated. Revisions shall be completed as necessary.
  - 5.2.8 Determining the mission, goals, and objectives of the facility;
  - 5.2.9 Ensuring that the physical environment protects the health and safety of patients, personnel, and the public;
  - 5.2.10 Establishing an organizational structure and specifying functional relationships among various components of the facility;
  - 5.2.11 Reviewing and approving the facility's training program for staff;
  - 5.2.12 Ensuring that all equipment utilized by facility staff or by patients is properly used and maintained per manufacturer's recommendations;
  - 5.2.13 Adopting, implementing and enforcing policies and procedures related to emergency planning and disaster preparedness. The governing body shall review the facility's disaster preparedness plan at least annually;
  - 5.2.14 Ensuring there is a quality assessment and performance improvement (QAPI) program to evaluate the provision of patient care. The governing body shall review and monitor QAPI activities quarterly;
  - 5.2.15 Reviewing legal and ethical matters concerning the facility and its staff when necessary and responding accordingly;
  - 5.2.16 Maintaining effective communication throughout the facility;
  - 5.2.17 Approving all contracts or arrangements affecting the medical care provided under its auspices;
- 5.3 There shall be a description of each type of service offered.
- 5.4 The governing body shall provide for full disclosure of ownership to the Department.

## **6.0 Administration/Personnel**

- 6.1 Director
  - 6.1.1 There shall be a full-time physician serving as director who is board certified in emergency medicine.
  - 6.1.2 The director shall have the overall authority and responsibility for the daily operation and management of the FSED.



6.1.3 The director shall be responsible for the direction, provision and quality of medical care.

6.1.4 The authority, duties and responsibilities of the director shall be defined in writing and shall include but not be limited to:

6.1.4.1 Interpretation and execution of the policies adopted by the governing body;

6.1.4.2 Program planning, budgeting, management and program evaluation;

6.1.4.3 Maintenance of the FSED's compliance with licensure regulations and standards;

6.1.4.4 Preparation and submission of required reports;

6.1.4.5 Distribution of a written plan for the delegation of administrative responsibilities and functions in the absence of the director;

6.1.4.6 Documentation of complaints relating to the conduct or actions by employees/contractors/medical staff and action taken secondary to the complaints;

6.1.4.7 Conducting or supervising the resolution of complaints received from patients regarding the delivery of care or services; and

6.1.4.8 Reviewing policies and procedures at least annually, and reporting, in writing, to the governing body on the review.

6.1.5 The director shall designate, in writing, a person who meets the director qualifications to act in the absence of the director.

## 6.2 Supervision of clinical services

6.2.1 The director shall appoint, in writing, a full-time employee as the clinical director.

6.2.2 The clinical director shall be responsible for implementing, coordinating and assuring quality of patient care services.

6.2.3 The clinical director shall:

6.2.3.1 Be a registered nurse with evidence of substantial education, experience and competence in emergency nursing. The Certified Emergency Nurse (CEN) credential is preferred, but not required; and

6.2.3.2 Show evidence of competence in management/administration/supervision of the clinical services of the FSED; and

6.2.3.3 Provide general supervision and direction of the services offered by the FSED.

6.2.4 The director shall designate, in writing, a person who meets the clinical director qualifications to act in the absence of the clinical director.

## 6.3 Contract services

6.3.1 The FSED maintains responsibility for all services provided to the patient.

6.3.2 Services provided by the FSED through arrangements with a contractor agency or individual shall be set forth in a written contract which clearly specifies:

6.3.2.1 The services to be provided by the contractor;

6.3.2.2 The necessity to conform to all FSED policies;

6.3.2.3 The procedure for annual assurance of clinical competence of all individuals utilized under contract;

6.3.2.4 The procedure for supervision of services of the contracted individuals; and

6.3.2.5 The frequency of contract renewal.

6.3.3 The FSED must ensure that personnel and services contracted meet the requirements specified in these regulations for FSED personnel and services.

## 6.4 Written policies

6.4.1 Policy manuals which outline the procedures and practices of the FSED shall be prepared and followed.

6.4.2 The FSED shall establish written policies which include:

6.4.2.1 Compliance with state licensure law;

6.4.2.2 Governing body and management;

6.4.2.3 Emergency services;

6.4.2.4 Quality assessment and performance improvement;

6.4.2.5 Environment;

6.4.2.6 Medical staff;

6.4.2.7 Nursing services;

6.4.2.8 Medical records;



- 6.4.2.9      Pharmaceutical services;
- 6.4.2.10     Laboratory and radiologic services;
- 6.4.2.11     Patient rights;
- 6.4.2.12     Infection control;
- 6.4.2.13     Patient admission, assessment, discharge and transfer;
- 6.4.2.14     The investigation and documentation of incidents, accidents and major adverse incidents;
- 6.4.2.15     Reporting of all reportable communicable diseases to the Department; and
- 6.4.2.16     Employment/Personnel. Such policies shall include:
  - 6.4.2.16.1    Qualifications, responsibilities and requirements for each job classification;
  - 6.4.2.16.2    Pre-employment requirements;
  - 6.4.2.16.3    Position descriptions;
  - 6.4.2.16.4    Orientation;
  - 6.4.2.16.5    In-service education;
  - 6.4.2.16.6    Annual performance review and competency testing; and
  - 6.4.2.16.7    The process of appointment to the professional staff whereby it can satisfactorily be determined that the individual is appropriately licensed and qualified for the privileges and responsibilities to be given.

6.4.3      Policies shall be made available to representatives of the Department upon request.

#### 6.5      Personnel records

- 6.5.1      Records of each employee/contractor shall be available upon request by authorized representatives of the Department.
- 6.5.2      For all employees/contractors, the FSED shall maintain current individual personnel records on-site which shall contain at least:
  - 6.5.2.1      Written verification of compliance with pre-employment requirements;
  - 6.5.2.2      Documentation of clinical competence;
  - 6.5.2.3      Evidence of current professional licensure, registration or certification as appropriate;
  - 6.5.2.4      Educational preparation and work history;
  - 6.5.2.5      Written performance evaluations conducted, at least, annually; and
  - 6.5.2.6      A written and signed job description.

#### 6.6      Staff development

- 6.6.1      All employees/contractors, including medical staff, are required to complete an orientation program.
  - 6.6.2      An orientation/training program should be based on an instruction plan that includes learning objectives, clinical content and minimum acceptable performance standards, and shall include but not be limited to:
    - 6.6.2.1      Organizational structure of the FSED;
    - 6.6.2.2      Patient care policies and procedures;
    - 6.6.2.3      Infection control;
    - 6.6.2.4      Philosophy of patient care;
    - 6.6.2.5      Patient rights;
    - 6.6.2.6      Personnel and administrative policies;
    - 6.6.2.7      Job description;
    - 6.6.2.8      Disaster preparedness; and
    - 6.6.2.9      Applicable state regulations governing the delivery of services.
  - 6.6.3      Documentation of orientation must include the date and hours, content, and name and title of the person providing the orientation.
  - 6.6.4      It is the responsibility of the FSED to ensure that employees/contractors are proficient to carry out the assigned care in a safe, effective and efficient manner. Nothing in these regulations is intended to restrict the practice of licensed independent practitioners practicing in accordance with Delaware law.
  - 6.6.5      All newly hired employees and contractors must have a written validation of competency upon orientation, prior to providing care to patients, and annually thereafter.
  - 6.6.6      Attendance records must be kept for all orientation and continuing education programs.
- #### 6.7      Medical Staff
- 6.7.1      Each physician practicing in the FSED shall be licensed to practice in this State and:
    - 6.7.1.1      Be board-certified in emergency medicine;



- 6.7.1.2 Be board-eligible for certification in emergency medicine and attain certification within three years of completion of a residency program; or
  - 6.7.1.3 Have at least three years of full-time clinical experience in emergency medicine within the past five years, be American Board of Medical Specialties or American Osteopathic Association certified in a medical specialty, and hold current certifications in advanced cardiac life support, advanced pediatric life support, and advanced trauma life support.
- 6.7.2 One (1) or more physicians shall be in attendance at the FSED at all times.
- 6.7.3 All members of the FSED medical staff must be:
  - 6.7.3.1 Individually credentialed to ensure the individual is deemed qualified; and
  - 6.7.3.2 Appointed to their position within the FSED by the governing body.
- 6.7.4 Medical staff privileges must be granted by the governing body, in writing.
- 6.7.5 Medical staff privileges must be reappraised by the FSED at least every 24 months.
  - 6.7.5.1 Reappraisals must include assessment of current competence by the FSED Director.
- 6.7.6 Resident physicians and non-physician providers may work in the FSED as long as there are procedures in place for prompt consultation and communication with an on-site physician.
- 6.7.7 If the FSED assigns patient care responsibilities to resident physicians or non-physician providers, it must have:
  - 6.7.7.1 Established credentialing and privileging procedures approved by the governing body; and
  - 6.7.7.2 Policies and procedures, approved by the governing body, for overseeing and evaluating clinical activities.
- 6.7.8 The medical staff shall adopt, implement and enforce written bylaws to carry out its responsibilities. The bylaws shall:
  - 6.7.8.1 Be approved by the governing body;
  - 6.7.8.2 Include a statement of the duties and privileges of each category of medical staff (i.e. active, consultant);
  - 6.7.8.3 Describe the organization of the medical staff; and
  - 6.7.8.4 Include criteria for privileges to be granted and a procedure for applying the criteria to individuals requesting privileges.
- 6.8 Nursing services
  - 6.8.1 There shall be an organized nursing services which must be under the direction of the clinical director.
  - 6.8.2 Each registered nurse practicing in the FSED shall:
    - 6.8.2.1 Be licensed as a registered nurse in this State;
    - 6.8.2.2 Hold, or attain within 6 months of hire, certifications, or the equivalents as approved by the Department, in advanced cardiac life support and pediatric advanced life support; and
    - 6.8.2.3 Hold and maintain current certification in Basic Cardiac Life Support.
  - 6.8.3 There must be sufficient nursing staff with the appropriate qualifications to ensure the nursing needs of all FSED patients are met.
  - 6.8.4 Patient care responsibilities must be delineated for all nursing service personnel.
  - 6.8.5 Nursing services must be provided in accordance with recognized standards of practice.
- 6.9 There must be at least one physician that meets the requirements set forth in these regulations, and one registered nurse with current certifications, or equivalents as approved by the Department, in advanced cardiac life support and pediatric advanced life support in the FSED at all times.
- 6.10 There shall be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.
- 6.11 Schedules, names, and telephone numbers of all physicians and others on emergency call duty, including alternates, shall be maintained. The facility shall retain all schedules for at least one year.

## **7.0 Emergency Services**

- 7.1 Adequate age-appropriate supplies and equipment shall be immediately available and in readiness for use.
  - 7.1.1 At a minimum, the age-appropriate equipment and supplies shall include:
    - 7.1.1.1 Emergency call system;
    - 7.1.1.2 Oxygen;
    - 7.1.1.3 Blood pressure monitoring equipment;
    - 7.1.1.4 Pulse oximeter, or similar device to measure blood oxygenation;



- 7.1.1.5 Mechanical ventilator assistance equipment, including airways, manual breathing bag, and mask;
- 7.1.1.6 Laryngoscopes and endotracheal tubes;
- 7.1.1.7 Tracheostomy trays;
- 7.1.1.8 Suction equipment and supplies;
- 7.1.1.9 Electrocardiograph;
- 7.1.1.10 Cardiac monitoring and defibrillator with battery pack;
- 7.1.1.11 Cardiac pacing system;
- 7.1.1.12 Central venous catheter trays;
- 7.1.1.13 Infusion pumps;
- 7.1.1.14 Intravenous fluids and administration sets;
- 7.1.1.15 Gastric lavage supplies, including large lumen tubes and bite blocks;
- 7.1.1.16 Urinary catheters and appropriate collection equipment;
- 7.1.1.17 Lumbar puncture sets;
- 7.1.1.18 Intraosseous needles and placement equipment;
- 7.1.1.19 Blanket warmer;
- 7.1.1.20 Emergency medications and supplies specified by medical staff;
- 7.1.1.21 Stabilization devices for spinal injuries; and
- 7.1.1.22 Emergency obstetrical pack.
- 7.2 Emergency equipment shall be tested and maintained in accordance with manufacturer's recommendations.
- 7.3 If the FSED does not provide diagnosis or treatment services to victims of sexual assault, the FSED must refer a victim seeking forensic medical examination to a hospital that provides services to those victims.
- 7.4 All patients discharged or transferred from the FSED must receive specific, printed, legible written aftercare instructions, including any referrals.

## **8.0 Infection Prevention and Control**

- 8.1 The FSED shall establish and implement an infection prevention and control program which shall be based upon nationally recognized infection prevention/control guidelines/standards (i.e. the Centers for Disease Control and Prevention).
- 8.2 The FSED must designate in writing, a qualified licensed healthcare professional who will lead the facility's infection prevention and control program. The FSED must determine that the individual has had training in the principles and methods of infection prevention and control.
  - 8.2.1 The individual designated to lead the FSED's infection prevention and control program must develop and implement a comprehensive plan that includes actions to prevent, identify and manage infections and communicable diseases. The plan of action must include mechanisms that result in immediate action to take preventive or corrective measures that improve the FSED's infection control outcomes.
- 8.3 The FSED must maintain an ongoing program to prevent, control and investigate infections and communicable diseases. As part of this program, the FSED must have an active surveillance program that covers both patients and personnel working in the FSED.
  - 8.3.1 The infection prevention and control program shall include policies and procedures including, but not limited to the following:
    - 8.3.1.1 A system for investigating, reporting and evaluating the occurrence of all infections or diseases which are reportable or conditions which may be related to activities and procedures of the facility and maintaining records for all patients or personnel having these infections, diseases or conditions;
    - 8.3.1.2 Care of patients with communicable diseases;
    - 8.3.1.3 Exclusion from work and authorization to return to work for personnel with communicable diseases;
    - 8.3.1.4 Surveillance techniques to minimize sources and transmission of infection;
    - 8.3.1.5 The collection, storage, handling and disposition of all pathological and infectious wastes within the facility and to be removed from the facility;
    - 8.3.1.6 Sterilization, disinfecting and cleaning practices and techniques used in the facility, including but not limited to:
      - 8.3.1.6.1 Care of utensils, instruments, solutions, dressings, articles and surfaces;



- 8.3.1.6.2 Selection, storage, use and disposition of disposable and non-disposable patient care items. Disposable items shall not be reused;
- 8.3.1.6.3 Methods to ensure that sterilized materials are packaged and labeled to maintain sterility and to permit identification of expiration dates;
- 8.3.1.6.4 Procedures for care of equipment and other devices that provide a portal of entry for pathogenic microorganisms;
- 8.3.1.6.5 Techniques to be used during each patient contact, including handwashing before and after each patient contact; and
- 8.3.1.6.6 Criteria and procedures for isolation of patients.

8.3.2 The infection prevention and control program should be specific to each particular area of the FSED.

- 8.4 The FSED must provide and maintain a functional and sanitary environment to avoid sources and transmission of infections and communicable diseases.
- 8.5 The FSED's infection prevention and control program must be integrated into its QAPI program. Infection control data and program activities are an ongoing component of the quality improvement program and actions are taken in response to the data analyses to improve the FSED's infection control performance.
- 8.6 Reportable diseases shall be reported to the Division of Public Health.
- 8.7 All FSED personnel shall receive orientation at the time of employment and annual in-service education regarding the infection prevention and control program.

## **9.0 Quality Assessment Performance Improvement**

- 9.1 The FSED shall develop, implement, maintain, and evaluate an effective, ongoing facility-wide, data driven, interdisciplinary QAPI program.
- 9.2 The QAPI program shall reflect the complexity of the facility's organization and services. All facility services (including those services furnished under contract or arrangement) shall focus on indicators related to improved health outcomes and the prevention and reduction of medical errors.
- 9.3 The FSED shall measure, analyze and track quality indicators or other aspects of performance that the facility adopts or develops that reflects processes of care and facility operations.
- 9.4 The facility's ongoing QAPI program shall include:
  - 9.4.1 An ongoing review of key elements of care using comparative and trend data to include aggregate patient data;
  - 9.4.2 Identification of areas where performance measures or outcomes indicate an opportunity for improvement;
  - 9.4.3 Appointment of an interdisciplinary team to:
    - 9.4.3.1 Identify, measure, analyze and track indicators for variation from desired outcomes;
    - 9.4.3.2 Create and implement improvement plan or plans;
    - 9.4.3.3 Evaluate the implementation of the improvement plan or plans; and
    - 9.4.3.4 Continue monitoring and improvement activities until resolution of the improvement plan.
  - 9.4.4 Establishment and monitoring of quality indicators related to improved health outcomes. For each quality assessment indicator, the facility shall establish and monitor a level of performance consistent with current professional knowledge. These performance components shall influence or relate to the desired outcomes themselves. At a minimum, the following indicators shall be measured, analyzed, and tracked on a monthly basis:
    - 9.4.4.1 Infection control (staff and patient screening, standard precautions);
    - 9.4.4.2 Adverse incidents;
    - 9.4.4.3 Mortality (review of each death and monitoring modality specific mortality rates);
    - 9.4.4.4 Complaints and suggestions;
    - 9.4.4.5 Staffing;
    - 9.4.4.6 Safety; and
    - 9.4.4.7 Clinical record reviews to include treatment and medication errors.
- 9.5 The facility shall continuously monitor performance, take actions that result in performance improvement and track performance to ensure that improvements are sustained over time. The facility shall immediately correct any identified problems that threaten the health and safety of patients.

## **10.0 Environment**



- 10.1 The FSED must have a safe and sanitary environment, properly constructed, equipped and maintained to protect the health and safety of patients and staff.
- 10.2 Linen and laundry services
  - 10.2.1 An adequate supply of clean linen or disposable materials shall be maintained.
  - 10.2.2 Clean linen shall be stored, handled and transported to prevent contamination.
  - 10.2.3 Linens shall be maintained in good repair.
  - 10.2.4 There shall be separate and distinct areas for the storage and handling of clean and soiled linens.
  - 10.2.5 Soiled linen shall be handled, transported, stored and processed in a manner to prevent leakage and the spread of infection.
  - 10.2.6 Soiled linen not processed on a daily basis must be stored in a separate properly ventilated storage area.
  - 10.2.7 Carts used to transport soiled linen must be constructed of impervious materials and must be cleaned and disinfected after each use.
  - 10.2.8 Linen shall be processed according to nationally recommended standards for healthcare laundry.
  - 10.2.9 For laundry reprocessed off-site:
    - 10.2.9.1 The FSED must have a contract with a commercial or hospital laundry.
    - 10.2.9.2 Clean linens returned to the FSED must be completely wrapped or covered to protect against contamination.
- 10.3 Sanitation and housekeeping
  - 10.3.1 The FSED shall provide housekeeping services to maintain a clean, sanitary, safe environment which is free from odors.
  - 10.3.2 Treatment areas/rooms shall be thoroughly cleaned after each use.
  - 10.3.3 All cleaning materials, solutions, cleaning compounds and hazardous substances shall be:
    - 10.3.3.1 Properly identified;
    - 10.3.3.2 Stored in a safe place; and
    - 10.3.3.3 Stored separate from patient care items and food.
  - 10.3.4 Cleaning shall be performed in a manner which minimizes the spread of pathogenic organisms in the environment.
  - 10.3.5 The FSED shall be kept free of insects and rodents. A contract with a pest control agency shall be executed and available for review.
  - 10.3.6 Blood spills shall be cleaned immediately or as soon as is practical with a disposable cloth and an appropriate chemical disinfectant.
    - 10.3.6.1 The surface shall be subjected to intermediate level disinfection in accordance with the manufacturer's directions for use, if a commercial liquid chemical disinfectant is used.
    - 10.3.6.2 If a solution of chlorine bleach (sodium hypochlorite) is used, the solution shall be at least 1:100 sodium hypochlorite and mixed in accordance with the manufacturer's directions for use. The surface to be treated shall be compatible with this type of chemical treatment.
    - 10.3.6.3 The facility shall use dedicated cleaning supplies for the cleaning of blood spills.
- 10.4 Waste and waste disposal
  - 10.4.1 All waste receptacles shall be impervious, lined and clean.
  - 10.4.2 Waste receptacles shall be conveniently available in all toilet rooms, patient areas, staff work areas, and waiting rooms.
  - 10.4.3 All rubbish and refuse shall be collected, stored and disposed of in a manner designed to prevent transmission of disease.
  - 10.4.4 The provisions of the State of Delaware, Department of Natural Resources and Environmental Control, Regulations Governing Solid Waste, 7 **DE Admin. Code** 1301, are hereby adopted as the regulatory requirements for FSEDs in Delaware and are hereby referred to, and made part of this Regulation, as if fully set out herein.
  - 10.4.5 Regulated waste must be placed in an approved "red" bag which is marked with the International Biohazard Symbol. It must then be disposed of by a waste hauler approved by the Delaware Department of Natural Resources and Environmental Control. Sharps ready for disposal shall be disposed of in approved sharps containers. Contaminated waste which does not release liquid blood or body fluids when compressed or does not release dried blood or body fluids when handled may be placed in a receptacle and disposed of through normal, approved disposal methods.



## **11.0 Medical Records**

- 11.1 The FSED shall develop and maintain a system for the collection, processing, maintenance, storage, retrieval, authentication and distribution of patient medical records. Records may exist in hard copy, electronic format, or a combination of the two media.
- 11.2 An accurate and legible medical record must be maintained on every individual receiving care in the FSED.
- 11.3 Medical records shall be protected from loss, tampering, alteration, improper destruction, and unauthorized or inadvertent use.
- 11.4 The FSED shall ensure that each medical record is treated with confidentiality and is maintained according to professional standards of practice.
- 11.5 The FSED shall designate a person to be in charge of medical records. This person's responsibilities include, but are not limited to:
  - 11.5.1 The confidentiality, security, and safe storage of medical records;
  - 11.5.2 The timely retrieval of individual medical records upon request;
  - 11.5.3 The specific identification of each patient's medical records;
  - 11.5.4 The supervision of the collection, processing, maintenance, storage, retrieval, and distribution of medical records; and
  - 11.5.5 The maintenance of a predetermined organized medical record format.
- 11.6 Medical records shall be retained in a retrievable form until destroyed.
  - 11.6.1 Medical records of adults (18 years of age and older) shall be retained for a minimum of five (5) years after the last date of service before being destroyed.
  - 11.6.2 Records of minors (less than 18 years of age) shall be retained for a minimum of five (5) years after the patient reaches 18 years of age.
  - 11.6.3 The FSED shall not destroy medical records that relate to any matter that is involved in litigation if the facility knows the litigation has not been fully resolved.
  - 11.6.4 All records must be disposed of by shredding, burning or other similar protective measure in order to preserve the patient's right to confidentiality.
  - 11.6.5 The FSED must establish procedures for the notification to patients regarding the pending destruction of the medical records.
  - 11.6.6 Documentation of medical record destruction must be maintained by the FSED.
- 11.7 If the FSED plans to close, the facility shall notify the Department in writing at the time of closure of the disposition of the medical records, including where the medical records will be stored, and the name, address, and phone number of the custodian of the records.
- 11.8 Each time the patient visits the FSED the medical record shall contain sufficient accurate information. This information must include, but is not limited to:
  - 11.8.1 Complete patient identification;
  - 11.8.2 Date, time and means of arrival and transfer or discharge;
  - 11.8.3 Allergies and untoward reactions to drugs recorded in a prominent and uniform location;
  - 11.8.4 A complete description of any care given to the patient before the patient's arrival at the facility;
  - 11.8.5 Pertinent history of the illness or injury and results of the physical examination, including the patient's vital signs;
  - 11.8.6 A complete detailed description of treatment and procedures performed in the FSED;
  - 11.8.7 Clinical observations including the results of treatments, procedures, and tests;
  - 11.8.8 Diagnostic impressions;
  - 11.8.9 All medication and treatment orders signed by the prescribing physician or non-physician provider;
  - 11.8.10 All medications administered, including the drug name, dose, route of administration and time of administration;
  - 11.8.11 All medications dispensed to the patient by the FSED, including the drug name, dose, route and frequency of administration;
  - 11.8.12 Documentation of a properly executed informed consent when necessary;
  - 11.8.13 For patients with a length of stay greater than eight (8) hours, an evaluation of nutritional needs and evidence of how identified needs were met;
  - 11.8.14 Evidence of evaluation of the patient by a physician or non-physician provider prior to discharge or transfer; and



- 11.8.15 Conclusion at the termination of evaluation ~~[and/or or]~~ treatment, including final disposition, the patient's condition on discharge or transfer, and any instructions given to the patient or family for follow-up care.
- 11.9 All entries in the medical record shall be legible, accurate, complete, dated, timed and authenticated by the person responsible for providing or evaluating the service provided no later than 48 hours after discharge.
- 11.10 To ensure continuity of care, summaries or photocopies of the patient's medical record shall be transferred to the facility where future care will be rendered.
- 11.11 The FSED shall maintain the following:
- 11.11.1 A log identifying each individual who presents to the FSED for treatment and services including name, date and the time of arrival.
- 11.11.2 Statistical information concerning admissions, transfers, discharges, deaths and adverse incidents required for the effective administration of the facility.

## **12.0 Pharmaceutical Services**

- 12.1 The FSED shall provide drugs, controlled substances and biologicals in a safe and effective manner in accordance with acceptable standards of practice.
- 12.2 The FSED must maintain compliance with all state and federal laws, regulations and guidelines governing pharmaceutical services.
- 12.3 The FSED must be properly registered under State and Federal Controlled Substance Acts.
- 12.4 Drugs, controlled substances and biologicals shall be properly stored and accessible only to authorized personnel.
- 12.4.1 Schedule II medication must be under double lock.
- 12.5 Drugs, controlled substances and biologicals must be prepared and administered according to acceptable standards of practice.
- 12.6 Verbal orders must be countersigned by the prescriber within 48 hours of receipt.

## **13.0 Laboratory and Radiologic Services**

- 13.1 The FSED shall provide on-the-premises clinical laboratory services and diagnostic radiology services during all hours of operation.
- 13.2 Laboratory Services
- 13.2.1 Clinical laboratory services shall include collection, processing and provision of results to meet a patient's emergency laboratory needs.
- 13.2.2 Laboratory Services shall comply with the Clinical Laboratory Improvement Amendments of 1988 (CLIA 1988), in accordance with the requirements specified in 42 Code of Federal Regulations §§493.1 – 493.1780.
- 13.2.3 When blood and blood components are stored, the FSED shall have written procedures readily available containing directions on how to maintain the blood and blood components within permissible temperatures and including instructions to follow in the event of a power failure or other disruption of refrigeration.
- 13.2.3.1 Blood transfusions shall be prescribed in accordance with facility policy and administered in accordance with a written protocol for the administration of blood and blood components and the use of infusion devices and ancillary equipment.
- 13.2.3.2 Personnel administering blood transfusions and intravenous medications shall have special training for this duty according to adopted, implemented, and enforced facility policy.
- 13.2.3.3 Blood and blood components shall be transfused through a sterile, pyrogen-free transfusion set that has a filter designed to retain particles potentially harmful to the recipient.
- 13.2.3.4 Facility staff must observe the patient for potential adverse reactions during the transfusion and for an appropriate time thereafter, and document the observations and patient's response.
- 13.2.3.5 Pre-transfusion and post-transfusion vital signs shall be recorded.
- 13.2.3.6 Following the transfusion, the blood transfusion record or copy shall be made a part of the patient's medical record.
- 13.2.4 The FSED shall establish a mechanism for ensuring that the patient's physician or other licensed health care professional is made aware of critical lab value results, as established by the medical staff, before or after the patient is discharged. A physician or non-physician practitioner shall read, date, sign and authenticate all laboratory reports.
- 13.3 Radiology Services



- 13.3.1 The FSED shall provide radiological services including but not limited to: x-ray, computed tomography scan and ultrasound.
- 13.3.2 The radiology department shall meet all applicable federal, state and local laws, codes, rules, regulations and ordinances.
- 13.3.3 The FSED must adopt and implement policies and procedures that provide safety for patients and personnel, including but not limited to:
  - 13.3.3.1 Adequate shielding for patients, personnel and surrounding areas;
  - 13.3.3.2 Labeling of radioactive materials, waste and hazardous areas;
  - 13.3.3.3 Transportation of radioactive materials between locations within the FSED;
  - 13.3.3.4 Security of radioactive materials, including determining who may have access to radioactive materials and controlling access to radioactive materials;
  - 13.3.3.5 Testing of equipment for radiation;
  - 13.3.3.6 Maintenance of personal radiation monitoring devices;
  - 13.3.3.7 Proper storage of radiation monitoring badges when not in use;
  - 13.3.3.8 Storage of radio nuclides and radio pharmaceuticals as well as radioactive waste; and disposal of radio nuclides, unused radio pharmaceuticals, and radioactive waste; and
  - 13.3.3.9 Methods of identifying pregnant patients.
- 13.3.4 Policy and procedure manuals shall include procedures for all examinations performed, infection control for the facility, treatment/examination rooms, dress codes of personnel, and cleaning of equipment.
- 13.3.5 The FSED must have policies and procedures in place to ensure that periodic inspections of radiology equipment are conducted and current, and that problems identified are corrected in a timely manner. The FSED must ensure that equipment is inspected in accordance with manufacturer's instructions, federal and state laws, regulations, guidelines and FSED policy.
- 13.3.6 Employees/contractors must be checked periodically, by use of exposure meters or badge tests, for amount of radiation exposure.
- 13.3.7 Radiology services shall only be performed upon a written order of a physician or non-physician practitioner.
- 13.3.8 A physician shall read, date, sign and authenticate all examination reports.

#### **14.0 Patient Rights**

- 14.1 The FSED must provide the patient, or patient's representative verbal and written notice of the patient's rights in a language and manner that the patient or patient representative understands.
- 14.2 The patient's rights shall be posted in a conspicuous place in the facility's waiting room and must include the address and telephone number of the Department to which patients may report complaints.
- 14.3 The patient has the right to:
  - 14.3.1 Be treated with respect, consideration and dignity;
  - 14.3.2 Receive care in a safe setting;
  - 14.3.3 Be provided appropriate privacy;
  - 14.3.4 Be free from abuse, neglect and exploitation;
  - 14.3.5 Be provided to the degree known, appropriate information concerning their diagnosis, treatment, and prognosis. When it is medically inadvisable to give such information to a patient, the information shall be provided to a person designated by the patient or to a legally authorized person;
  - 14.3.6 Be given the opportunity to participate in decisions involving the health care, except when the patient's participation is contradicted for medical reasons; and
  - 14.3.7 Voice grievances regarding treatment or care that is (or fails to be) furnished.
- 14.4 Information shall be available to patients and staff concerning:
  - 14.4.1 Patient rights;
  - 14.4.2 Patient conduct and responsibilities;
  - 14.4.3 Services available at the facility;
  - 14.4.4 Fees for services;
  - 14.4.5 Payment policies; and
  - 14.4.6 Methods for expressing complaints and suggestions to the facility.
- 14.5 Patient records shall be treated confidentially.



- 14.6 Incidents of abuse, neglect, exploitation and unprofessional conduct shall be reported to the Department and appropriate regulatory agency.
- 14.7 Any person associated with the FSED who reasonably believes or knows of information that would reasonably cause a person to believe that an incident of abuse, neglect or exploitation perpetrated by any person has, is or will occur shall report the incident to the Department and appropriate regulatory agency.
- 14.8 Any person associated with the FSED who reasonably believes or knows of information that would reasonably cause a person to believe that the facility or an employee or health care professional associated with the facility has, is, or will be engaged in conduct that is or might be illegal, unprofessional, or unethical and that relates to the operation of the facility shall report the information to the Department and appropriate regulatory agency.

## **15.0 Disaster Preparedness**

- 15.1 The FSED shall implement written procedures which describe staff and patient actions to manage potential medical and non-medical emergencies, including but not limited to fire, equipment failure, power outages, medical emergencies, and natural or other disasters which are likely to threaten the health, welfare, or safety of facility patients, staff, or the public.
- 15.2 The FSED shall maintain a disability inclusive written disaster preparedness plan for natural and other disasters specific to the facility. The plan shall be based on an assessment of the probability and type of disasters in the region and the local resources available to the facility.
  - 15.2.1 Contact shall be made annually with the local disaster management representative to assess the need to revise the plan and to ensure that local agencies are aware of the facility, its provision of life-saving treatment, and the patient population served.
  - 15.2.2 The plan shall include:
    - 15.2.2.1 Procedures to minimize harm to patients and staff along with ensuring safe facility operations;
    - 15.2.2.2 Provisions for responsibility of direction and control, communications, alerting and warning systems, evacuation, and closure.
  - 15.2.3 The FSED shall designate in writing a person to monitor and coordinate disaster preparedness activities.
  - 15.2.4 The FSED shall maintain documentation of the monitoring and coordination of disaster preparedness activities.

## **16.0 Fire Safety**

- 16.1 The FSED shall comply with the rules and regulations of the State Fire Prevention Commission.
- 16.2 The FSED must be inspected annually by the fire marshal having jurisdiction, and all applications for license (new and renewal) must include documentation, dated within the past 12 months, indicating compliance to all applicable fire code regulations.
- 16.3 Failure to provide documentation from the fire marshal having jurisdiction, dated within the past 12 months, indicating compliance to all applicable fire code regulations shall be grounds for licensure action.
- 16.4 An evacuation floor plan shall be prominently and conspicuously posted for display throughout the facility in areas that are readily visible to patients, staff, and visitors.
- 16.5 All employees shall be trained in procedures to be followed in the event of a fire or fire-related emergency. Training shall be:
  - 16.5.1 Part of the initial employee orientation; and
  - 16.5.2 Conducted annually thereafter.
- 16.6 The FSED shall conduct one fire drill per shift per quarter.
  - 16.6.1 Fire drills shall include the transmission of the fire alarm signal and simulation of the emergency fire condition, simulation of evacuation of patients and other occupants, and use of fire-fighting equipment.
  - 16.6.2 Written reports shall be maintained to include evidence of patient and staff participation.

## **17.0 Severability**

Should any section, sentence, clause or phrase of these regulations be legally declared unconstitutional or invalid for any reason, the remainder of said regulations shall not be thereby affected.